

Remarks

Claims 1-20 are pending in this application.

Before discussing the rejections, Applicants deem it prudent to set forth what they consider to be invention.

The present invention is a lanolin-free lanolin substitute which comprises:

- A) from about 5 to about 95% by weight of at least one plant sterol fatty acid ester;
- B) from about 1 to about 20% by weight of at least one polyglyceryl dipolyhydroxy fatty acid ester;
- C) from about 1 to about 20% by weight of at least one polyglyceryl di-fatty acid ester; and
- D) from about 0.25 to about 10% by weight of at least one glyceryl fatty acid ester.

The composition can optionally contain:

from about 1-80% by weight of an additive containing a mixture of

- (i) a vegetable oil,
- (ii) a hydrogenated vegetable oil, and
- (iii) a non-petroleum desired wax.

Other optional components F), G), and H) can be present in the composition.

The compositions of the invention can be used as a much less expensive substitute for lanolin in all products that include lanolin as a component, including but not limited to, pharmaceuticals, leather-finishing compositions, soaps, detergents, cosmetic compositions, e.g. face creams, facial tissues, hair-set compositions and sun-tan preparations.

Appl. No.: 10/686,478
Response dated December 7, 2006
Reply to Office Action of August 23, 2006

INFORMATION DISCLOSURE STATEMENT

Applicants have submitted an Information Disclosure Statement on October 14, 2004, citing U.S. 4,868,220 and U.S. 6,316,030 cited in the PCT Search Report. To Applicants' knowledge, there are no references cited in the specification. Applicants will appreciate receiving an acknowledgement from the Examiner that the Information Disclosure Statement has been received and considered.

CO-PENDING APPLICATIONS

Applicants and the Examiner are aware of U.S. Serial Number 10/303,149 filed March 20, 2003, which claims subject matter closely related to the subject matter claimed in the present application.

REJECTIONS UNDER 35 U.S.C. § 112 - FIRST PARAGRAPH SCOPE OF ENABLEMENT REJECTIONS

At the beginning of the rejection, the Examiner cites the contents of 35 U.S.C. § 112 - First Paragraph. Applicants submit that the specification contains a written description of the invention and the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art, to which it pertains, or with which it is most nearly connected, to make and use the same and sets forth the best mode contemplated by the inventor, at the time the application was filed, for carrying out the invention.

The invention is a lanolin substitute which does not contain lanolin but which is useful for the same uses as lanolin. Applicants herewith submit page 681 from Hawley's Condensed Chemical Dictionary, 12th edition. Hawley's Condensed Chemical Dictionary discloses that lanolin is useful in ointments, leather finishes, soaps, face creams, facial tissues, hair-set, and suntan preparations.

The lanolin substitute is prepared by mixing the various ingredients set out in the

claims by methods which are well known by one skilled in the art, that is, merely by mixing. The composition is useful for any of the uses for which lanolin is generally applied. These uses are associated with topical applications to the skin as a base for ointments, lotions, soaps, and the like. The composition of the invention and lanolin generally is not associated with major effects on the body functions or body chemistry and is not a medicament. The efficacy of lanolin is not related to specific chemical action in the body but to a general gentle emollient effect due to its physical properties. That is, it is an oil-like material but can contain substantial amounts of water which is not apparent.

Applicants invite the Examiner's attention to page 1090 of Hawley's Condensed Chemical Dictionary, Twelfth Edition, which describes "sterol" as a steroid alcohol. Such alcohols contain a common steroid nucleus, plus an 8 to 10-carbon-atom side-chain and a hydroxyl group. Sterols are widely distributed in plants and animals both in the free form and esterified to fatty acids. Near the bottom of the right-hand column of page 1090, the structure of stigmasterol is set out. At page 681, bottom of the left-hand column, the structure of lanosterol is set out (not a plant sterol). And at page 1042 the structure of sitosterol is set out. One can look at these structures and they all contain a basic steroid nucleus with an 8 to 10-carbon-atom side-chain and a hydroxyl group. As can be seen by one skilled in the art, these compositions are very similar and one skilled in the art would expect that their physical properties would be similar. That is, when incorporated into an ointment, face cream, facial tissues, hair-set and suntan preparations, would be expected to provide similar properties to the composition. The present invention does not rely upon the chemical reaction of the lanolin-substitute with a skin to which the lanolin substitute is applied, but to utilize the known physical properties of lanolin, such as an emollient to incorporate these properties into the skin.

The Examiner states that the composition can contain thousands of variations which are not disclosed in the specification. Applicants submit that there are a number

of phytosterols, but these compounds are closely related in relation to their physical properties. The different phytosterols can be chemically reacted with other materials to form a broad range of steroid-like compositions. However, the present invention does not rely upon the chemical reaction of the phytosterols useful in the practice of the present invention. Applicants therefore respectfully submit that the use of phytosterol esters with the fatty acids disclosed in the specification are fully supported in the specification and claims as originally filed.

In addition, the formulation of the lanolin substitute is merely a mixing process (see page 4, lines 17, 18 for the preparation of the composition). The other components in the lanolin substitute of the present invention, are common materials in cosmetic and care formulating chemistry and one skilled in the art having before him the present application would have no difficulty in formulating a useful lanolin substitute which falls within the metes and bounds of the claims.

In rejecting the claims, the Examiner is apparently requiring that Applicants do a PhD thesis to provide examples of all of the possible combinations of the substituents useful in the practice of the present invention. Since the present invention does not rely upon sophisticated chemistry, but relies upon the physical properties of the components useful in the present invention, one skilled in the cosmetic or care product formulation art would have no difficulty in combining the components to provide a useful lanolin substitute within the limitations of the claims in the present application.

The specification provides a clear description of each and every component which is incorporated into the lanolin substitute. Applicants submit that this is a sufficient disclosure to permit anyone skilled in the cosmetic or care product formulation art to provide a useful lanolin substitute within the composition of the present invention.

Applicants submit that one skilled in the art could take any sterol fatty acid ester as described in the specification and merely mix it with the other components which are fully set forth in the specification, to arrive at a useful lanolin substitute. The lanolin

substitute of the invention utilizes the physical attributes of lanolin rather than utilize it in a sophisticated chemical reaction. Therefore, one skilled in the art would have no difficulty in preparing a composition which had the physical properties which are required by the person preparing the formulation of the invention. Applicants submit that no undue experimentation would be required.

In making the rejection, the Examiner has failed to consider the requirements of 35 U.S.C. 112, second paragraph, which states:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which Applicant regards as his invention."

Applicants respectfully submit that the claims as presently in the application fully comply with the requirements of 35 U.S.C. 112, first paragraph, and the requirements of 35 U.S.C. 112, second paragraph, in claiming what Applicants consider to be their invention. Applicants submit that the Examiner appears to be requiring Applicants to claim what the Examiner considers to be the invention.

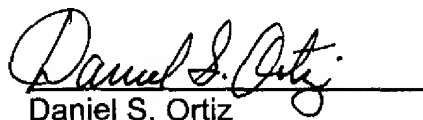
In view of the simple nature of the subject matter of the application, Applicants respectfully submit that the Examiner's rejection is untenable and respectfully request that the rejection be reconsidered and withdrawn. In reviewing the rejection, Applicants respectfully request that the Examiner look at the structures of the various sterols which Applicants have submitted from Hawley's Condensed Chemical Dictionary, and note that the structures of the sterols are very closely related and one skilled the art would have no difficulty in preparing the lanolin substitute of the present invention.

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Applicants note with appreciation that claims 3 and 4 are objected-to but would be allowable if independently written.

Respectfully submitted,

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Enc.: Hawley's Condensed Chemical Dictionary, Twelfth Edition; pages 681, 1042 and 1090